REMARKS/ARGUMENTS

These remarks are filed in response to the Examiner's Report of June 3, 2008, a response to which is due by September 3, 2008. In accordance with the provisions of 37 C.F.R. 1.136(a), it is respectfully requested that a three month extension of time be granted in which to respond to the outstanding Office Action mailed June 3, 2008, said period of response being extended from September 3, 2008 to December 3, 2008. Our deposit Account No. 13-2400 is being charged in the amount of $555 to cover the required extension fee for a small entity.

No new matter is added by the present amendments. Claims 29-39, 41-43 and 48 stand.

35 USC 103

The Examiner has rejected claims 29-39, 41-46 and 48 under 35 USC 103(a) as being unpatentable over Mezei et al. (U.S. Patent No. 5,451,408) or Mezel et al. (RE 38,407) in view of Dershwitz et al. and Shafer et al. Applicant has cancelled claims 44-46, rendering this rejection with regards to those claims moot.

The Examiner confirms that Mezei/Mezel lacks the express teaching of (1) continuous inhalation via a pulmonary drug delivery device, (2) administration is solely through the conscious effort of the user, (3) device mass of 250-2,500 gm (4) an outlet in the device through which the formulation is dispensed and (5) the intended pharmacokinetic profile of the claimed formulation upon administration. The Examiner states that these deficiencies are obvious per the teachings of Mezei/Mezel and/or are obviated by the teachings of Dershwitz and Shafer. Applicant respectfully traverses, with a special emphasis on the first two of these factors, namely continuous inhalation via a pulmonary drug delivery device and administration solely through the conscious effort of the user. With respect to these two points, the Examiner contends that continuous inhalation until sufficient analgesia is achieved would be prima facia obvious because opioids are indicated for the treatment of pain and as such would be

administered in amounts and frequencies needed for a given patient to obtain adequate pain relief. Regarding administration solely through the conscious effort of the user, the Examiner has not specifically and directly addressed why this is obvious in his finding of prima facia obviousness rational and motivation. However, indirectly, the Examiner contends that it is conventional for inhalation devices to comprise outlets from which aerosolized formulations are delivered to a patient for inhalation. The Examiner also contends that optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired result. The Examiner contends that the optimization of ingredient amounts would have been obvious at the time of applicant's invention and the claimed invention as a whole would have been prima facia obvious to one of ordinary skill in the art because the combined teachings of the prior art is fairly suggestive of the claimed invention.

With regards to the second of these two express teachings, i.e. administration is solely through the conscious effort of the user, applicant respectfully submits that there are considerable differences between the presently claimed invention and the state of the prior art. Applicant has amended claim 37 to clarify that this self administration by the patient is a key inventive step in the claimed invention. One of the key distinctions between the present invention and the prior art is that, in the prior art, patients are medicated by attending professionals. For example, in Mezei, as well as Dershwitz and Shafer, it was specifically taught, or would be inferred by a person skilled in the art, that a professional would decide on the dosing amount and would medicate the patient. This professional involvement requires time, energy and judgement calls on the part of the professional when determining how much medication to dispense, since an individual's perception of pain, and an individual's reaction to opioids for the mitigation of said pain, vary radically from one person to another. In the present invention, the medication process is controlled solely by the pain sufferer. The risk to a self medicating pain sufferer is, of course, the pain relief could be experienced only after the patient has dosed themselves to opioid levels that are toxic, given the delay in the

onset of opioid affects. This is addressed in the present invention by providing a composition that allows the patient to experience pain relief during a dosing session. That dosing session can then be stopped by the user before ingesting toxic amounts of the opioid.

The invention is unique and unobvious in providing a system by which the end-user can be responsible for medicating themselves to reduce pain using opioids that risk significant toxicity upon overdose. The present system takes drug and dosing into consideration to allow end-users to experience pain relief and/or side affects that are the patient's key to stop dosing and avoid toxicity.

This is therefore a specialized field of medicine, pulmonary delivery of toxic opioids to manage pain. Moreover, the present invention contemplates a method that allows and enables the pain sufferer and user to take responsibility for dosing, with attendant risk of overdose. This overdose risk is mitigated when the method is applied using the present opioid composition and delivery system. Other approaches, including all of the approaches cited by the Examiner, use either professional managed care or instrumentation to intervene or control the user's intake of the medicine.

Applicant submits that the presently claimed method is therefore both novel and unobvious over the prior art, since all of the prior art teaches against patient mediated and patient delivered opioid. Opioids are known in the prior art to have severe side affects, and doctor and/or professional monitoring of patients taking opioids was believed to be a necessary part of administering an opioid for pain relief. The present invention teaches against this by providing a method that allows a patient to self administer the opioid to affect. This invention is enabled by picking specific concentrations and ratios of opioids. However, these specific ratios and concentrations of opioids are not routine experimentation in that a person skilled in the art would not, ever, utilize routine experimentation to attempt to provide a formulation of opioid that can be taken by a patient without doctor intervention. The patient self administration to affect, by the patient understanding that they are to stop administration at the onset

of a side affect or upon pain relief, is a herebefore unseen, uncontemplated, likely unattempted, and thus unobvious method.

In order to clarify the ambit of protection sought, applicant has amended claim 37 to clarify that the claim is to a pain management method enabling a pain sufferer to self medicate by repeating dosing with an opioid formulation wherein the method relies solely on the actions of the pain sufferer to manage intake of said opioid during the medication process. Applicant has also limited the composition claims (claims 39, 41, 42, 43, 48 and 29-36) to make these claims dependent from claim 37, the method claim.

Double Patenting

The Examiner has rejected claims 29 and 48 under 35 USC 101 as claiming the same invention as that of claims 10 and 56 of co-pending application No. 10/788,466. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The Examiner contends that the cited claims of the instant application and co-pending '145 are semantically verbatim.

Applicant respectfully requests that the Examiner hold this rejection in abeyance until one of the two co-pending applications are in a form to be ready for allowance, at which point the applicant will address this rejection by either removing the duplicative claims or possibly even abandoning one of the two applications.

The Examiner has rejected claims 37-39, 41-45 and 48 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 10-25 of U.S. Patent No. RE 38,407 in view of Dershwitz et al. Applicant respectfully submits that the reasons for this double patenting rejection are identical to the reasons provided for the Examiner's 35 USC 103 rejection of these same claims. As such, applicant respectfully submits that the amendments and arguments presented above with respect to obviousness also address the

Examiner's rejections with respect to double patenting.

Conclusion

It is respectfully submitted that the present amendments and remarks herein are a complete response to all outstanding issues. Favourable consideration is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully Submitted,
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